

CLAIMS:

1. A method for repairing a vaginal wall which has been damaged by one or more prolapsed pelvic organs said method including:
 - 5 (a) mobilising the vaginal epithelium off the underlying fascia of at least a portion of the damaged vaginal wall;
 - (b) positioning a prosthetic material over the exposed fascia;
 - (c) re-fixing the vaginal epithelium over the prosthetic material and the fascia; and thereafter
 - 10 (d) locating an intra-vaginal splint into the vagina.
2. A method as claimed in claim 1 wherein the vaginal wall being repaired is the anterior vaginal wall and the vaginal epithelium is mobilised off the underlying fascia by incision and lateral dissection through the arcus tendineous fascia pelvie and continued towards the sacrospinous ligaments on both sides.
- 15 3. A method as claimed in claim 1 wherein the vaginal wall being repaired is the anterior vaginal wall and the vaginal epithelium is mobilised off the underlying fascia by incision and lateral dissection through the arcus tendineous fascia pelvie and into the paravaginal space on each side of the anterior vaginal wall.
- 20 4. A method as claimed in claim 3 wherein the said prosthetic material is a synthetic mesh having laterally extending arms on both sides and the said mesh is positioned over the exposed fascia of the anterior vaginal wall with each lateral arm of the mesh placed into tunnels extending from the anterior vaginal wall dissection into the paravaginal spaces.
- 25 5. A method as claimed in claim 1 wherein the vaginal wall being repaired is the posterior wall of the vagina and the vaginal epithelium is mobilised off the underlying fascia by incision and dissection laterally to the levator ani muscles on each side and in the upper part of the vagina in a lateral and cranial direction through the rectal pillars on both sides towards the sacrospinous ligaments on
- 30 each side of the vaginal wall.
6. A method as claimed in claim 5 wherein the prosthetic material is a synthetic mesh having upwardly extending arms and the synthetic mesh is positioned over the exposed fascia of the posterior vaginal wall with each

upwardly extending arm of the synthetic mesh being placed into the tunnel extending from the posterior vaginal wall dissection to the respective sacrospinous ligament.

7. A method as claimed in any one of the previous claims wherein said
5 prosthetic material once positioned over the exposed fascia of the vaginal wall being repaired is thereafter attached to the underlying fascia by sutures.

8. A method as claimed in any one of the previous claims wherein the
fascia of the damaged vaginal wall is plicated after the vaginal epithelium has
been mobilized but prior to the positioning of a prosthetic material over the
10 exposed fascia.

9. A method as claimed in any one of the preceding claims wherein the
intra-vaginal splint once located within the vagina is attached to the adjacent
vaginal epithelium by sutures.

10. A method as claimed in any one of claims 1 to 9 wherein said intra-
15 vaginal splint remains located within the vagina for a period of at least three
weeks following location within the vagina.

11. A method as claimed in claim 10 wherein said intra-vaginal splint
remains located within the vagina for a period of between 4 to 6 weeks following
location within the vagina.

20 12. A method for repairing the anterior and posterior vaginal walls of the
vagina damaged by one or more prolapsed pelvic organs, said method
including:

(a) mobilizing the vaginal epithelium off the underlying fascia of at
least a portion of the anterior vaginal wall;

25 (b) positioning a first prosthetic material over the exposed fascia of
the anterior vaginal wall;

(c) re-fixing the vaginal epithelium over the said first prosthetic
material and the fascia of the anterior vaginal wall;

(d) mobilizing the vaginal epithelium off the underlying fascia of at
30 least a portion of the posterior vaginal wall;

(e) position a second prosthetic material over the exposed fascia of
the posterior vaginal wall;

(f) re-fixing the vaginal epithelium over the second prosthetic material and the fascia of the posterior vaginal wall; and thereafter

(g) locating an intra-vaginal splint into the vagina.

13. A method as claimed in claim 12 wherein said intra-vaginal splint is
5 attached to the adjacent vaginal epithelium by sutures.

14. A method as claimed in either one of claims 12 or 13 wherein said intra-vaginal splint remains located within the vagina for a period of at least three weeks following location within the vagina.

15. A method as claimed in claim 14 wherein said intra-vaginal splint
10 remains located within the vagina for a period of between 4 to 6 weeks following location within the vagina.

16. A flexible synthetic mesh for use in the repair of a vaginal wall damaged by the prolapse of one or more pelvic organs said synthetic mesh including a plurality of open pores bounded by strands made of non-woven polymeric
15 material, wherein the junctions between the respective strands are without open interstices and wherein a majority of the open pores of the mesh have an area of less than 15 mm².

17. A flexible synthetic mesh as claimed in claim 16 wherein all of the open pores of the mesh have an area of less than 15 mm².

20 18. A flexible synthetic mesh as claimed in claim 16 wherein the majority of the open pores of the mesh have an area of less than 10 mm².

19. A flexible synthetic mesh as claimed in any one of claims 16 to 18 which incorporates a central body portion and two longitudinal side portions and in which the size of the open pores of the mesh in the central body portion is
25 greater than the size of the open pores of the mesh in the longitudinal side portions.

20. A flexible synthetic mesh as claimed in claim 19 wherein the area of each of the open pores in the central body portion is less than 10 mm² and the area of each of the open pores in the side portions of the mesh is less than 5 mm².

30 21. A flexible synthetic mesh as claimed in any one of claims 16 to 20 wherein the mesh has a weight of less than 0.0080 g/cm².

22. A flexible synthetic mesh as claimed in claim 21 wherein the weight of the mesh is between 0.0020 and 0.0050 g/cm².

23. A flexible synthetic mesh as claimed in any one of claims 16 to 22 wherein said mesh is substantially oval in shape with a first lateral arm extending from one side of the said mesh and a second lateral arm extending from the other side of said mesh.
- 5 24. A flexible synthetic mesh as claimed in any one of claims 16 to 22 wherein said mesh is substantially trapezium shaped with a first extension arm extending upwardly and at an angle away from one side portion of the mesh and a second extension arm extending upwardly and at an angle way from the other side portion of the mesh.
- 10 25. An intra-vaginal splint which includes two longitudinally extending side arms both having first and second ends, said side arms being connected at their respective first ends by a first connecting member and at their respective second ends by a second connecting member wherein said first and second connecting members are of different lengths.
- 15 26. An intra-vaginal splint as claimed in claim 25 is made from a flexible medical grade silicone.
27. An intra-vaginal splint as claimed in either claim 25 or claim 26 wherein said splint is substantially trapezium shaped.
28. An intra-vaginal splint as claimed in any one of claims 25 to 27 wherein
20 all or part of the interior of the splint is closed by a membrane.
29. An intra-vaginal splint as claimed in claim 28 wherein the membrane is twin walled and is inflatable.
30. An intra-vaginal splint as claimed in any one of claims 25 to 29 wherein the longitudinally extending side arms are disposed in a first plane in the portion
25 of the splint proximate the first connecting member and in a second plane, which is at an angle to the first plane, for the remaining portion of the intra-vaginal splint.
31. An intra-vaginal splint as claimed in claim 30 wherein the angle between the respective planes is between 8 to 15°.
- 30 32. An intra-vaginal splint as claimed in claim 31 wherein the angle between the respective planes is about 10°.
33. A method as claimed in any one of claims 1 to 15 wherein the prosthetic material is a flexible synthetic mesh as claimed in any one of claims 16 to 24.

34. A method as claimed in any one of claims 1 to 15 wherein the intra-vaginal splint is a splint as claimed in any one of claims 25 to 32.
35. A kit suitable for use in repairing a vaginal wall of the vagina of a woman suffering from pelvic organ prolapse; said kit including at least one piece of a
5 flexible synthetic mesh having a plurality of open pores bounded by strands made of non-woven polymeric material in which junctions between the respective strands are without open interstices and wherein a majority of the open pores of the mesh have an area of less than 15mm^2 and a range of three or more differently sized intra-vaginal splints.
- 10 36. A kit as claimed in claim 35 containing three or more intra-vaginal splints of the type claimed in any one of claims 25 to 32.
37. A kit as claimed in either one of claims 35 or 36 which contains at least one pre-shaped piece of flexible synthetic mesh as claimed in claim 23 and at least one pre-shaped piece of flexible synthetic mesh as claimed in claim 24.
- 15 38. A kit as claimed in any one of claims 35 to 37 also including written directions to use the flexible synthetic mesh and the intra-vaginal splints of the said kit in accordance with a method as claimed in any one of claims 1 to 15, 33 or 34.
39. A method substantially as hereinbefore described with particular
20 reference to what is shown in any one or more of the drawings.
40. A flexible synthetic mesh substantially as hereinbefore described with reference to what is shown in Figure 9.
41. A flexible synthetic mesh substantially as hereinbefore described with reference to what is shown in Figure 10.
- 25 42. An intra-vaginal splint substantially as hereinbefore described with reference to what is shown in any one of Figures 11 to 17.